

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.**

**REMARKS**

Applicants submit this Amendment in reply to the Office Action dated June 19, 2003.

As an initial matter, Applicants have amended the inventorship to delete Scott J. WOLF and Peter J. WILK because the inventions of these individuals are no longer being claimed. A Petition Under 37 C.F.R. §1.48(b) requesting the deletion of the Scott J. WOLF and Peter J. WILK from this application is submitted herewith. The inventive entity of the instantly claimed invention should thus be as follows:

Todd A. HALL, Greg R. FURNISH, Simon M. FURNISH, David Y. PHELPS, and Vincent POMILI.

Applicants also respectfully request acknowledgement of the Information Disclosure Statement filed on April 24, 2003, and the return of the attached PTO Form 1449 with appropriate notations indicating that the listed documents were considered by the Examiner. For the Examiner's convenience, Applicants submit herewith a copy of the PTO Form 1449 submitted on April 24, 2003, as well as a date-stamped postcard indicating receipt of the Information Disclosure Statement by the PTO on that date.

Before entry of this Amendment, claims 69-108 were pending in this application. After entry of this Amendment, claims 69-79 and 81-108 remain pending in this application.

Claim 80 has been cancelled without prejudice or disclaimer. Applicants request withdrawal of the § 112 rejection set forth in the Office Action.

FINNEGAN  
HENDERSON  
FARABOW  
GARRETT &  
DUNNER LLP

1300 I Street, NW  
Washington, DC 20005  
202.408.4000  
Fax 202.408.4400  
www.finnegan.com

In the Office Action, the Examiner rejected claims 69-74, 76-70, and 81-93 under 35 U.S.C. § 102(e) as being anticipated by Maki et al. (U.S. Patent No. 6,261,260) ("Maki"), and rejected claims 94-108 under 35 U.S.C. § 103(a) as being unpatentable over Maki in view of Wilk (U.S. Patent No. 5,429,144).

Of the claims rejected based on Maki, claims 69, 82, and 94 are independent. Independent claim 69 is directed to a delivery catheter comprising, among other aspects, "a steering member being configured to cooperate with a body lumen of a patient to turn the distal end of the catheter." Independent claim 82 is directed to a method of turning a distal end of a catheter within a body lumen comprising, among other aspects, "actuating a steering member... wherein the steering member when actuated cooperates with the body lumen to turn the distal end of the catheter." Independent claim 94 is directed to a method for delivering a medical device and also recites, among other aspects, a "steering member cooperating with a wall of the body lumen."

Maki discloses a shaft tube 3 for insertion into a living body having a cylindrical balloon 4 that is liquid-tightly connected to the periphery of the tip of the shaft tube 3. (Col. 9, lines 9-14). The balloon has two relatively low stretchable sections 1A, 1B, and a relatively high stretchable section 2. (Col. 7, lines 55-60). When the balloon is injected with fluid, the high stretchable section 2 expands more than the low stretchable sections 1A, 1B, and thus causes the tube to become bent into an S-shaped form toward the sides of the relatively low stretchable sections 1A, 1B. (Col. 2, lines 64 - 68; col. 13, lines 51-62). The extent of the bending can be continuously adjusted by changing the magnitude of the fluid pressure. (Col. 13, lines 61-62).

Contrary to the Examiner's assertion at page 3 of the Office Action, however, Maki does not teach that any portion of the balloon in Fig. 11 "push[es] against opposite sides of the vessel wall to steer the catheter tip." Indeed, the Examiner has pointed to no disclosure in Maki to support this conclusory assertion. Instead of teaching that the balloon 4 pushes against or otherwise cooperates with the vessel wall to steer the shaft tube 3, Maki discloses that the bending of the tube 3 is due to the interaction between the fluid pressure applied to the balloon 4 and the high and low stretchable sections, and not any alleged cooperation between the balloon 4 and any type of vessel wall. (Col. 2, lines 64 - 68; col. 13, lines 51-62). Thus, Maki fails to disclose or otherwise suggest either "a steering member being configured to cooperate with a body lumen of a patient to turn the distal end of the catheter," as recited in claim 69, "actuating a steering member... wherein the steering member when actuated cooperates with the body lumen to turn the distal end of the catheter," as recited in claim 82, or a "steering member cooperating with a wall of the body lumen," as recited in claim 94.

Indeed, Maki teaches away from such steering members configured to cooperate with body lumens to turn a distal end of a catheter, as set forth in claims 69, 82, and 94. For example, one of the stated objectives of the Maki device is to provide a "multi-functional catheter designed from the viewpoint of the non-transluminal approach." (Col. 2, lines 2-4; emphasis added).

For at least the above reasons, claims 69, 82, and 94, and their respective dependent claims are patentably distinguishable from Maki and Applicants request the withdrawal of the § 102 rejection based on Maki. Moreover, Applicants request the withdrawal of the § 103 rejection based on Maki in view of Wilk because Wilk fails to cure the above-noted deficiencies of Maki. Indeed, the Examiner does not assert otherwise in the Office Action.

Also in the Office Action, claims 69-78 and 81-93 were rejected under 35 U.S.C. § 102(b) as being anticipated by Grinfeld et al. (U.S. Patent No. 5,312,344) ("Grinfeld"). Applicants respectfully traverse the rejection based on Grinfeld because Grinfeld does not teach each and every aspect of claims 69-78 and 81-93 and therefore does not anticipate those claims.

As discussed above, independent claim 69 recites, among other aspects, "a steering catheter... configured to cooperate with a body lumen of a patient to turn the distal end of the catheter" and independent claim 82 recites, among other aspects, "actuating a steering member... wherein the steering member when actuated cooperates with the body lumen to turn the distal end of the catheter."

Grinfeld discloses an arterial perfusion catheter or cannula (a) with either one or two balloons (9, 10) connected to it. (Col. 2, lines 54-55). Grinfeld discloses introducing the catheter (a) into an ascending aorta (3) with the balloons (9, 10) deflated, and once the catheter (a) is positioned, inflating the balloons (9, 10) in order to occlude the arterial vessel (A) in the ascending aorta (3). (Col. 2, line 62 - col. 3, line 22). In this way, Grinfeld teaches that the vessel can be perfused.

Contrary to the Examiner's assertion at page 3 of the Office Action, however, Grinfeld neither discloses nor otherwise suggests that the balloons (9, 10) connected to the catheter(a) are in any way used to "redirect and steer the catheter as it moves through the ascending aorta." The Examiner has pointed to no disclosure whatsoever to support this assertion. Rather, as mentioned above, Grinfeld discloses that the balloons (9, 10) are not inflated until after the catheter (a) is positioned. As such, Grinfeld teaches that positioning, and thus steering of the catheter (a), occurs independently of the balloons and while the balloons (9,10) are in a deflated configuration and not engaged with the vessel walls. Moreover, this explicit teaching of Grinfeld directly contradicts the Examiner's assertion at page 3 of the Office Action that "the catheter is pushed while the balloons are in the inflated state."

Thus, Grinfeld neither discloses nor otherwise suggests that the balloons (9, 10) "turn the distal end of the catheter" or do anything else other than temporally occlude the ascending aorta (3). For at least this reason, claims 69 and 82, and their respective dependent claims, are patentably distinguishable from Grinfeld and Applicants request that the § 102 rejection based on Grinfeld be withdrawn.

Dependent claims 70-79, 81, 83-93, and 95-108 depend either directly or indirectly from one of claims 69, 82, and 94, and thus are allowable for at least the same reasons claims 69, 82, and 94 are allowable. In addition, at least some of the dependent claims recite unique combinations that are neither taught nor suggested by the art and therefore at least some also are separately patentable.

Applicants respectfully request the withdrawal of the outstanding rejections and the timely allowance of claims 69-79 and 81-108.

The Office Action contains characterizations of the claims and the related art with which Applicants do not necessarily agree. Unless expressly noted otherwise, Applicants decline to subscribe to any statement or characterization in the Office Action.


In discussing the specification, claims, abstract, and/or drawings in this Amendment, it is to be understood that Applicants are in no way intending to limit the scope of the claims to any exemplary embodiments described in the specification or abstract and/or shown in the drawings. Rather, Applicants are entitled to have the claims interpreted broadly, to the maximum extent permitted by statute, regulation, and applicable case law.

Please grant any extensions of time required to enter this Amendment and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: September 17, 2003

By:   
Michael W. Kim  
Reg. No. 51,880

FINNEGAN  
HENDERSON  
FARABOW  
GARRETT &  
DUNNER LLP

1300 I Street, NW  
Washington, DC 20005  
202.408.4000  
Fax 202.408.4400  
www.finnegan.com